JAN 2 8 2002

SEAL POLYMER INDUSTRIES SDN. BHD.
Lot 72706, Jalan Lahat Kawasan Perindustrian Bukit Merah
31500 Lahat, Perak
Tel : 605 – 322 3200, Fax : 605 – 322 2300

K014055

1.0 **SMDA 510 (K) SUMMARY**

2.0	Submitter	SEAL POLYMER INDUSTRIES SDN BHD Lot 72706, Jalan Lahat Kawasan Perindustrian Bukit Merah 31500 Lahat, Perak. Malaysia
	Tel	(60 5) 322 3200
	Fax	(60 5) 322 2300
	Name of Contact Person	Ms. CHUN CHOO FONG
	Date of Summary Prepared	November 15, 2001
3.0	**Name of Device**	
	Trade Name	Cashmere Non-Sterile, Powdered Latex Examination Gloves
	Common Name	Exam Glove
	Classification Name	Powdered Patient Examination Glove

4.0 Identification of the Legally Marketed Devices

Class 1 Powdered Latex Patient Examination Glove 80 LYY, powdered with absorbable dusting powder, which meets all the requirements of ASTM Standard D3578-99 and FDA requirements.

5.0 Description of The Device

Class 1 Powdered Latex Patient Examination Glove 80 LYY, powdered with absorbable dusting powder, which meets all the requirements of ASTM Standard D3578-99 and FDA Water Leak Test.

6.0 The Intended Use of Glove

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

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7. Summary of Performance Data:

Performance data of gloves based on ASTM D3578-99 and FDA 1000 ml watertight test.

TEST	ASTM D3578-99	CASHMERE LIGHTLY POWDERED LATEX EXAM GLOVES
1. Watertight (1000 ml)	G I AQL=2.5%	Pass GI AQL=2.5%
2. Length (mm) Size XS S M L XL	 Min 230 Min 230 Min 230 Min 230 Min 230	 240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL	 - 80 +/- 10 95 +/- 10 111 +/- 10 -	 <80 82 – 88 92 – 98 102 – 108 >110
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.08 Min 0.08	 0.10 minimum 0.10 minimum
5. Physical Properties **Before Aging** Tensile Strength (Mpa) Ultimate Elongation (%) **After Aging** Tensile Strength (Mpa) Ultimate Elongation (%)	 Min 14 Min 700 Min 14 Min 500	 27.1* 917.5* 24.9* 880*
6. Powder Content	-	Below 200 mg / glove
7. Protein Content	-	Below 200 microgram / gram

* These figures were the average among the eight tested samples. Please refer to Attachment B2.

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8. The performance data of the glove as showed above meet the ASTM D3578-99 Standard and FDA's requirement.
Powder content is below 200 mg per glove, which meet the FDA Requirements.

9. The Biocompatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Biocompatibility Tests.

10. Conclusion

We concluded that the Cashmere Non-Sterile, Lightly Powdered Latex Examination Gloves meet:

- ASTM D3578-99 Standard
- FDA pinhole requirements
- FDA minimum powder residual content

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2002

Mr. Chun C. Fong
Seal Polymer Industries Sdn. Bhd.
Lt 72706, Jalan Lahat, Kawasan
Perindustrain Bukit Merah
Lahat, Ipoh, Perak,
MALAYSIA

Re: K014055
Trade/Device Name: Non-Sterile Powdered Latex Examination Gloves with a Protein Labeling Claim (200 Micrograms orLess)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: December 4, 2001
Received: December 10, 2001

Dear Mr. Fong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant : Seal Polymer Industries Sdn. Bhd.

510(K) Number: K014055

Device Name : Cashmere Non-Sterile, Powdered Latex Examination Gloves With Protein Labeling Claim (200 micrograms or less)

Indication For Use:

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patients' body, fluids, waste

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Concurrence of CDRH Office of Device Evaluation (ODC)

Prescription Use: ..... OR Over-The-Counter .....X.....
Per 21 CFR 80.109

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014055